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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,306	06/12/2001	Katy Drieu	00537/168002	3283
37903	7590	09/21/2005	EXAMINER	
DAWN JANELLE AT BIOMEASURE INC. 27 MAPLE STREET MILFORD, MA 01757			JAGOE, DONNA A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,306

Applicant(s)

DRIEU, KATY

Examiner

Donna Jagoe

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claims 12-15 are pending in this application.

Response to Arguments

Applicant's arguments filed 17 May 2005 have been fully considered but they are not persuasive. The rejection made in the paper mailed 21 July 2004 under 35 U.S.C. §103(a) over Ramwell et al U.S. Patent No. 5,002,965 is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth below.

Claims 12-15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Ramwell et al. U.S. Patent No. 5,002,965. Ramwell discloses applicant's preferred ginkgolides (i.e. claim 14 - Ginkgolide A and claim 15 - Ginkgolide B) for use in preventing or reducing reperfusion injury in organ transplantation. Applicant's claims differ in that they require a pharmaceutical composition. However, since the claimed ginkgolides have a known therapeutic use, one of ordinary skill in the art would have been motivated to employ the compounds in a pharmaceutical composition. The intended use of inhibiting membrane expression of a benzodiazepine receptor, an inhibiting of glucocorticoid release, or elevating ACTH levels does not distinguish the claims from the prior art since product claims are not limited by an intended use. It is a well-settled proposition of patent law that the intended utility of an already well-known composition does not render the composition patentable. Applicants' attention is drawn to In re Dillon, 16 USPQ2d 1897 at 1900 (CAFC 1990). The court sitting en banc ruled that the recitation of a new utility for an old and well-known composition does not render that composition new.

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Applicant argues that since the claims point to an "effective amount" of a ginkgolide and that "effective amount" is a distinguishing factor for compositions formulated for a particular use. In response to applicant's argument that "an effective amount" is a distinguishing factor for the composition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the ginkgolides of Ramwell et al. are capable of performing the intended use of treating a patient secreting a high-level of one or more glucocorticoids suffering from Cushings syndrome, stress-induced hypercortisolism or brain aging, then it meets the claim. Moreover, the dosages of Ramwell et al. overlap and encompass the instantly claimed doses (see column 2, lines 19-23).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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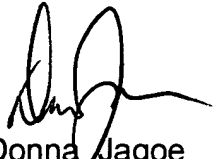
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Donna Jagoe
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Art Unit 1614


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09/13/2005